

Indiana Board of Pharmacy 402 West Washington Street, W072 Indianapolis, IN 46204 Phone: 317-234-2067

Fax: 317-233-4236

E-mail: pla4@pla.in.gov Like Us on Facebook

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Providing Industry Information with a Community Approach

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Important News Update

Board Launches Info on Remote Locations

Last month, we launched a new feature to provide more information about using Remote Locations connected to institutional facilities. You can find this info on our website under our "Licensee Information" link. If you or your facilities use remote locations,

frequently asking or are questions concerning remote locations, please refer to this link for more information. If you have additional input or questions, please refer them to our group inbox at pla4@pla.in.gov. The link for site is: http://www.in.gov/pla/3181.htm.

Ongoing Renewal Information

We are in the last few weeks of Pharmacist Intern renewals. If you have not received your intern renewal form you may either contact our office at pla4@pla.in.gov or by phone at (317) 234-2067.

Comments from Inspect

INSPECT For those individuals or facilities required to report data related to dispensing of controlled substances. INSPECT's deadline for pharmacies to achieve compliance for reporting data in the newly required ASAP 2007 format was April 1st, 2011. After that date facilities not uploading data in the correct format according to statute, (within seven days of the dispensation of a controlled substance, and every seven days) are subject to disciplinary action by the Board of Pharmacy. As of April 1st the PMP system is no longer able to accept any files in the previous ASAP 95 format, files MUST now be submitted in the newly required format. Our new requirements and formatting information can be found at www.in.gov/inspect

Remember that any uploaded file must be reviewed the next

day to see if there are any errors present (missing invalid information.) These errors can be corrected by viewing your uploaded file and re-submitting either corrected records or manually correcting the error through the PMP Portal. Pharmacies which submit data but do not correct errors within that data are in violation of IC 38-47-7-8.1, irrespective of whether they reported in a timely manner or not. A violation of statute or failure to achieve full compliance can result in discipline ranging from Personal Appearance before the Board, to failed inspections, and up to, but not limited to, fines and possible suspension or revocation of the dispensing license. If you are a Qualifying you Pharmacist then are directly responsible for assuring that your licensed pharmacy complies with the reporting requirements. Failure

to act can also result in discipline against your individual license if corrective action is not taken in a timely manner.

However, If you are still having issues with your file uploads or error correction, please email inspect@pla.in.gov and attach a copy of your file, and provide the login name and short description of the problem you are encountering. Issues will be addressed in the order they are received. As always we remain committed to assisting you in any way we can and encourage you to contact our office if you're experiencing difficulties.





Indiana Board of Pharmacy

Pharmacy Board Members

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Phil Wickizer	Director
Amy Phillips	Asst. Director
Stacie Barclay	Litigation Specialist
Regina Stigger	Case Manage
Deborah Mattingly	Case Manager
Anita Lovejoy	Case Manager

Compliance Officers

Eric Pearcy - South - 317.753.4025
Tim Thomas - East - 317.753.4000
Zaneta Nunnally - West - 317.753.3890
Wanda Levendoski - North - 317.753.4131

INSPECT

Josh KlatteProgram Director

INSPECT Phone Number: 317-234-4458
Email: inspect@pla.IN.gov
Fax: 317-233-4236

Suggestions and Comments

Anita Lovejoy, Editor alovejoy@pla.in.gov

Notes from the Director, Phil Wickizer Board and Attorney General Partner on Take Back Legislation

I wanted to take the opportunity this month to discuss some pending legislation of interest to the pharmacy world that the Board actively helped to create and support. That is House Bill 1121 (a.k.a., the "Take Back" Unused Medication. authored by Rep. Mahan (R), and co-authored bν Representatives: Brown (D). Frye (R), and Reske (D), passed out of the Senate Health and Provider Services Committee on Wednesday April 6, 2011 (having already passed House out of the of back Representatives February 2011). Its Senate Sponsors included Senators Banks, Breaux, Delph, and Miller. HB 1121 is the prescription drug take back legislation sponsored on behalf the Indiana Attorney General's Office and Indiana Board of Pharmacy.

HB 1121 is designed to allow the market and local communities to take an active role in sponsoring and utilizing take back programs to help combat prescription drug abuse and protect our most vulnerable populations. The Bill is also designed to help consumers be active participants in protecting our environment by using safe and appropriate disposal methods for unneeded and/or unwanted medications. Our goal is to create law and regulation that proactively encourage both institutional and

retail pharmacies to engage in take-back programs without the threat of unwarrented liability, and to offer their customers and communities a much needed service that gives back to the community and protects the environment.

As a Board, our primary mission is to protect consumers and promote public safety and patient health. Studies and recent reports and surveys show that one of the biggest threats to public health facing Indiana (and the nation as a whole) is the exponential rise in prescription drug abuse. While the growth of and availability of prescription drug use has contributed in a positive fashion quality of life for the overwhelming majority of people. it has also had disastrous consequences after being abused by unintended users.

Specifically, narcotics abuse among younger generations has risen at an alarming rate. We statistically know that approximately 70% of first time use and/or non-medical prescription use/abuse of narcotics occurs as a result of individuals obtaining unused prescriptions drugs from friends and family members (not from diversion or illicit sale). This occurs both knowingly (individuals willingly sharing drugs - i.e., "pharm" parties) or by unknowing means (theft from an unlocked medicine cabinet). want the Pharmacv Community to be proactive in reducing the opportunities for non-medical abuse alleviating the excess supply kept in homes and medicine cabinets. At the same time, we want to help educate the community and make sure drugs are disposed of in an environmentally friendly manner that won't damage our water systems or end up in landfills.

As of today, the Bill awaits a final concurrence in the House of Representatives and then will go to the Governor's desk for signature. For more detailed information on the status of this Bill, go to the following website: http://www.in.gov/apps/lsa/session/ billwatch. As more legislation is introduced, passed, will attempt to signed, we provide an update via the monthly newsletter and Facebook page.



Message from the Board, Donna S. Wall, PharmD, BCPS Ensuring the Integrity of Drug Distribution

Educate yourself!

The internet is a powerful tool for learning more about pharmaceuticals and their distribution. The following are internet websites that provide a wealth of information on this important topic.

Food and Drug Administration

The federal government regulatory agency. Provides upcoming information on regulations, drug approvals, drug safety alerts, and other industry information.

http://www.fda.gov

<u>Drug Information Online</u> <u>Drugs.com</u>

Provides information on the major pharmaceutical manufacturers. The site includes a Pill Identifier Wizard which assists the user identify a pill buy size, shape, color and number stamped on the pill.

http://www.drugs.com

National Association of Boards of Pharmacy

Provides credentialing services, testing, and license monitoring for the Pharmacy Industry.

http://www.nabp.net

The US drug distribution system has traditionally been one where the pharmacist has assumed the distribution was handled in a straight forward, transparent, and safe manner. Pharmacists tend to believe the typical distribution process involves a drug product leaving the manufacturer, goes to a drug distributor, followed by distribution to a pharmacy and patient. What is now very apparent is that neither of these statements is completely true.

Unfortunately for the patient and pharmacist, the distribution system has in many ways become а complex commodities market with much buying and selling of the product in an attempt to maximize profit and to cover shortages of certain prescription drugs. The following link is to an article that will provide a as to how off perspective course and dangerous some components of the distribution process have become: http://www.fiercepharmamanufa cturing.com. As a result of the situations described in the article. Indiana pharmacists should be aware and informed on the drug distribution process and what they can do to obtain safe product.

In 2006, the Indiana Legislature adopted laws requiring drug product to follow a normal chain of distribution. The normal chain of distribution concept mandates that drug distribution from manufacturer to end user

be а basic. simple. and (See transparent process. Indiana Code § 25-26-14). If a product cannot be obtained in such a manner, than the product must have an attached pedigree. The pedigree should state where the drug has traveled, who has handled it. and the lot numbers involved. This law was enacted to provide basic information to pharmacist and patient about product procurement.

Unfortunately, today there are still few unwelcome participants and bad actors in the distribution channels that care only about profit and nothing for patients (see article). Because of these bad actors. the pharmacist should always be on guard and very cautious when obtaining medications from unknown sources, from sources with deals that are much better than the regular market, and the selling of drugs in short supply from suppliers who happen to have it when no one else does. In these situations, the pharmacist must do their due diligence to assure that they are not being duped into buying contaminated or counterfeit drugs.

Accordingly, the Indiana Legislature went a step further and proactively provided pharmacists another tool with which to measure quality and ensure integrity of products being shipped by drug wholesalers into or out of Indiana. That tool is the VAWD

program established by the National Association of Boards of Pharmacy (VAWD=Verified-Accredited Wholesale Distributor). program is an independent accreditation program offered through NABP. The establishment of this requirement for mandatory accreditation requires drug wholesalers to demonstrate that facilities and drug handling meet practices nationally established safety standards.

Today, when a facility is granted VAWD accreditation, pharmacists have greater levels of assurance that the drug wholesaler has met auality standards and conducting their business in a manner that protects patients and the consumer. Indiana is one of the few states that mandates that all drua wholesalers servicing the state are accredited. The Indiana mandate has changed the wholesale drug business across the US and now VAWD is considered a standard for partaking in the wholesale drug distribution business. If a pharmacist is reviewing an unfamiliar drug distributor from which to purchase prescription medications and that it has VAWD accreditation, the pharmacist can have confidence that the wholesaler's business practice been reviewed compliance with Indiana laws and regulations. 🐺

Indiana Security Features For Prescriptions

All controlled substance prescriptions written by licensed Indiana practitioners, as defined by IC 16-42-19-5, must contain the following security features:

VOID PATTERN

(1) A latent, repetitive "Void" pattern screened at five percent (5%) in reflex blue must appear across

the entire face of the document when the prescription is photocopied.

WATERMARK ON BACKSIDE

(2) There shall be a custom artificial watermark printed on the back side of the base paper so that it may only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Indiana Security Prescription", appearing horizontally in a step-and-repeated format in five (5) lines on the back of the document using 12-point Helvetica bold type style.

RX SYMBOL

(3) An opaque RX symbol must appear in the upper right-hand corner, one-eighth (1/8) of an inch from the top of the pad and five-sixteenths (5/16) of an inch from the right side of the pad. The symbol

must be three-fourths (3/4) inch in size and must disappear if the prescription copy is lightened.

CHECK BOXES

(4) Six (6) quantity check-off boxes must be printed on the form and the following quantities must appear and the appropriate box be checked off for the prescription to be valid:

- (A) 1-24
- (B) 25-49 (C) 50-74
- (D) 75-100
- (E) 101-150
- (F) 151 and over

Compliance Calling, Wanda Levendoski, Compliance Officer-North 90 Day Prescriptions

Among the many questions the Indiana Board of Pharmacy Compliance Officers have been receiving from pharmacies, pharmacists, and law enforcement concern how to deal with multiple scripts for a CII and whether or not you can give or take scripts that amount to a 90 day supply of a particular CII. Customers will also ask, "can I get a 90 day script for my CII?" The answer is yes! This can be done in one of two ways and the decision is up to the prescribing physician.

Method Number One: The first way to accomplish giving a patient a 90 day script for a CII (that is also the most common) is for the physician to give the patient three separate scripts, each for a 30 day supply, providing the specific dates and notations that pertain to each 30 day supply. They do this with the following CFR;

PART 1306--PRESCRIPTIONS

- 1. The authority citation for part 1306 continues to read as follows:
 Authority: 21 U.S.C. 821, 21
 U.S.C. 829, 21 U.S.C. 871(b), unless otherwise noted.
- 2. Section 1306.12 is revised to read as follows:

<u>Sec. 1306.12</u> Refilling prescriptions; issuance of multiple prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

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(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

- (i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
- (ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;
- (iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
- (iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
- (v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.
- (2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing

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NO ADVERTISEMENTS

(5) No advertisements may appear on the front or back of the prescription blank.

ONE INCH SQUARE FOR LOGOS

(6) Logos, defined as a symbol utilized by an individual, professional practice, professional association, or hospital, may appear on the prescription blank. The upper left one (1) inch square of the prescription blank is reserved for the purpose of logos. Only logos, as defined by this subdivision, may appear on the prescription blank.

ONE PRESCRIPTION PER BLANK

(7) Only one (1) prescription may be written per prescription blank. The following statement must be printed on the bottom of the pad: "Prescription is void if more than one (1) prescription is written per blank."

REFILL OPTIONS

(8) Refill options that can be circled by the prescriber must appear below any logos and above the signature lines on the left side of the prescription blank in the following order:

Refill NR 1 2 3 4 5 Void after

Refill NR 12345 Void after _____

NAME AND LICENSE NUMBER

(9) Practitioner name and state issued professional license number must be preprinted, stamped, or manually printed on the prescription.

SIZE OF PRESCRIPTION BLANK

(10) All prescription blanks printed under this rule shall be four and one-fourth (4 1/4) inches high and five and one-half (5 1/2) inches wide.

See Illustration on this Page

Continued from page 4

Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

 3. <u>Section 1306.14</u> is amended by adding a new paragraph (e) to read as follows:

Sec. 1306.14 Labeling of substances and filling of prescriptions.

(e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

Dated: November 7, 2007.

Method Number Two: if the physician feels it is in the best interest of the patient they may provide 1 prescription for a 90 day supply. This option is available but less commonly used and presents greater risks for misuse and diversion. Physicians and pharmacies should ensure proper documentation is in place before writing and dispensing a 90 day supply. Proper risk management will prevent liability for all parties involved.

Federal Register Notice published on August 26, 2005 (DEA-271N), which clarifies limits on the amounts of c/s that may be prescribed on a single CII prescription.

"4. The CSA and DEA regulations contain no specific limit on the number of days worth of a schedule II controlled substance that a physician may authorize per prescription. Some states, however, do impose specific limits on the amount of a schedule II controlled substance that may be prescribed. Any limitations imposed by state law apply in addition to the corresponding requirements

under Federal law, so long as the state requirements do not conflict with or contravene the Federal requirements. 21 U.S.C. 903. Again, the essential requirement under Federal law is that the prescription for a controlled substance be issued for a legitimate medical purpose in the usual course of professional practice. In addition, physicians and pharmacies have a duty as DEA registrants to ensure that their prescribing and dispensing of controlled substances occur in a manner consistent with effective controls against diversion and misuse, taking into account the nature of the drug being prescribed. 21 U.S.C. 823(f). "**

Prescription Pad Illustrations

Front 1



Back 1

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Useful Pharmacy Links

BOP Homepage

INSPECT

Report Theft or Loss of Controlled Substance

Board Meeting Dates

Board Minutes and Agenda

Pharmacy Laws and Regulations

Indiana Code and the Indiana Administrative Code

Office of the Attorney
General

License Litigation
Search

FAQ: Asked and Answered

Q: How will I get notice when my license is issued, or when it is time for renewal?

A. The primary communication method for almost all types of notifications is via email. It is very important to establish, maintain and monitor email posts, especially during initial license application and license renewal processes. Most of our notification procedures through automated our licensing database, and posted without case manager input. Applicants and licensees miss out on important information when email is not checked regularly. Setting up an email account is easy, and free if services like MSN using hotmail. Google gmail, Windows live, or Yahoo ymail.

Q: How long does it take to get my license card after I get my license approved?

Immediately! That is because the Board no longer mails license cards licensees. This practice was discontinued in December 2009 in the Board's continuing efforts to create a paperless office. streamlining thereby the licensing process. Upon receipt of notice that an application for licensing is approved (see the question above for notice procedures), the licensee can go to the Board's website, www.bop.in.gov, click on the Services.IN.gov/License Express

link, found on the top left side of the page, and click the link(s) based on the service of choice.

To order your license card, click

"Order License Card." Once on the order license page, click "Get Started>>", and you will be on the "Welcome to MyLicense Online License / Permit Services" page. To log in, enter vour license number in full, and then the last four digits of your social security number and click enter. Then you will see your license information on the "MyLicense Online Licensing" page. In the left column of the page, click the Order License option. Then you will see the page "Available License(s) For Duplication", from here click "continue". Now you will see vour license information. Select either "Free Paper Certificate Printout" "License or Expiration Date", then enter the quanity desired (usually 1), and last, click on "Add to Shopping Cart". You will see the order in the text box below. Last, click on "Next Step - Checkout". The free paper printout will appear. To order a blue card, select "License w/expiration" and follow the promts.

QUICK TIP: Less is more when search parameters entering "Free Search under "Pharmacy Verifiv"! Select Board" in the "Profession" field drop down list. After that, do not use too many search items, often the last name and initial of the first name with an asterisk after is more than enough to call up an individual record (e.g. [Last Name:] Smith, [First J*). Name:] For facility searches, enter the name only. with an asterisk at the end (e.g. [Facility Name:] Big Pharmacy*). If the license

number is available or known, use that only. The data provided has to exactly match the data in the record, or an error message appears that says the record does not exist when in fact it does. Caveat! When using the verification please note page, individual licensees and facility licensees use different pages. The page will state in the header which search page is currently loaded. If it is the wrong one, a link in the page will take you to the correct search page.

From our readers:

Q. Could you clarify the regulations on faxed and e-prescriptions, should they be called on? (from Gloria Krejsa RPh)

A. (by Phil Wickizer, Board Director) Currently, you cannot do eprescribe for controls, period. We are working to change the legislature as we want to push e-prescribe. Stay tuned for more on that in the coming months. On faxes for controls, follow standard rules, but look for the original signatures signatures can't be electronic signature. For more detail, go to our E-prescribe web article. You can also contact your local pharmacy compliance officer.

Thank you to Gloria Krejsea for her question! If you have questions you would like to see published here, or comments on this article, you can submit a request to the following email address:

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pla4@pla.in.gov : Subject – Newsletter.

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